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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,394	03/27/2007	Alastair Edwin McAuley	1171/45543/173-PCT-US	8072
279 7590 12/24/2009 TREXLER, BUSHNELL, GIANGIORGI, BLACKSTONE & MARR, LTD. 105 WEST ADAMS STREET SUITE 3600 CHICAGO, IL 60603				
EXAMINER				
LOUIS, LATOYA M				
ART UNIT		PAPER NUMBER		
4177				
NOTIFICATION DATE		DELIVERY MODE		
12/24/2009		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ptodocket@trexlaw.com

### Office Action Summary

**Application No.**

10/599,394

**Applicant(s)**

EDWIN MCAULEY ET AL.

**Examiner**

LATOYA LOUIS

**Art Unit**

4177

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 September 2006.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1-18 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.  
10) ☒ The drawing(s) filed on 27 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO/GS/US)  
Paper No(s)/Mail Date 9/27/06  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

1. In response to the Preliminary Amendment filed on September 27, 2006, claim 19 has been cancelled and claims 1-18 are pending.

***Specification***

2. The abstract of the disclosure is objected to because the abstract should be in narrative form and generally limited to a single paragraph on a separate sheet. Correction is required. See MPEP § 608.01(b).

3. The disclosure is objected to because of the following informalities: The term "This application is a 371 of PCT/NZ05/00062 filed on March 30, 2005 which claims the foreign of New Zealand Application No. 532108 filed on April 2, 2004, which are incorporating by reference in its entity." Should be recited on Pg. 1, line 1, so as to update the status. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Kwok et al. (US Pat. No. 6,513,526 B2).

Regarding claim 1, Kwok et al. discloses a breathing assistance apparatus (Figs. 1, 3 and 6) for use with delivery of respiratory gases to a patient comprising: a patient interface (60A), having a body section (46) adapted to cover the nose (Fig. 4), or nose and mouth (Fig. 17) of the patient, a sealing interface (cushion 30A as sealing surface), including at least an outer sealing member (frame 32 as outer sealing member), the outer sealing member adapted to attach to the body section (46) in a sealing manner (col. 4, lines 24-28, 60-63), the outer sealing member (32) having a substantially thin section in at least its nasal bridge region (thin section 'A' is in the nasal bridge region), the thin section ('A') being substantially thinner than the rest ('B') of the outer sealing member, wherein the outer sealing member (32) is adapted to seal around the facial contours of the patient (col. 5, lines 18-38) thereby providing a sealed fluid communication to the respiratory tract of the patient (col. 5, lines 5-17).

Regarding claim 2, Kwok et al. discloses that the rest ('B') of the outer sealing member (32) is at least twice the thickness of the thin section (as seen from Fig. 6, 'B' is at least twice the thickness of 'A').

Regarding claim 3, Kwok et al. discloses in fig. 6 that the thickness ('B') of the rest of the outer sealing member (32) gradually increases from the thin section ('A') to the periphery ('P') of the outer sealing member (as shown, the thickness of frame 32 as outer sealing member increases from thin section 'A' to the periphery 'P').

Regarding claim 4, Fig. 17 of Kwok et al. discloses that the patient interface is a full face mask (col. 5, lines 49-56).

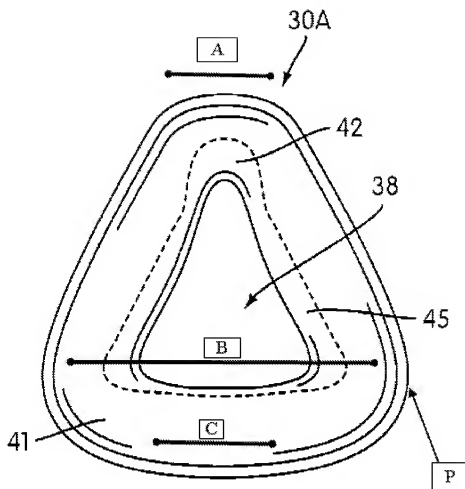


FIG. 6

Regarding claim 5, Kwok et al. discloses in figs. 6 and 12-13 that the outer sealing member (32) includes a second thin section ('C') in the region of the outer sealing member (32) that rests against the chin of the patient in use (see Fig. 17 showing the mask resting against the chin of a patient), the second thin section ('C') being substantially thinner than the rest ('B') of the outer sealing member (as shown in Figs. 6 and 13, the chin contacting region thin section 'C' is substantially thinner than the thickness 'B' of the rest of the outer sealing member 32).

Regarding claim 6, Fig. 4 of Kwok et al. discloses that the patient interface is a nasal mask (col. 4, lines 19-24).

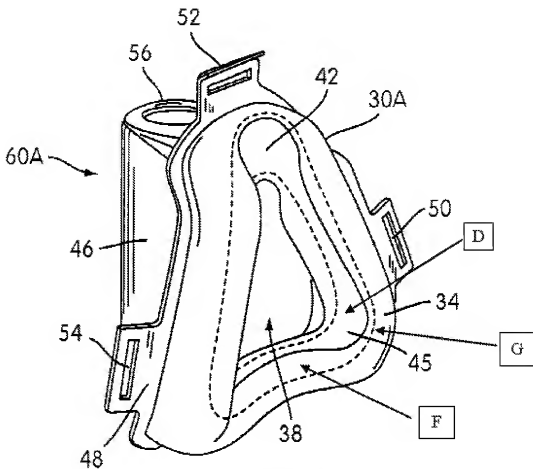


FIG. 3

Regarding claim 7, Kwok et al. discloses that the sealing interface (30A) includes an inner sealing member (membrane 34 as inner sealing member) fittable into the outer sealing member (32; col. 4, lines 40-44) and the inner sealing member (34) has a cut out region (42) in the nasal bridge region (col. 4, lines 35-39).

Regarding claim 8, Fig. 3 of Kwok et al. discloses that the inner sealing member (34) has

a cut out region ('D') in the cheek region (see col. 5, lines 24-27, 39-42).

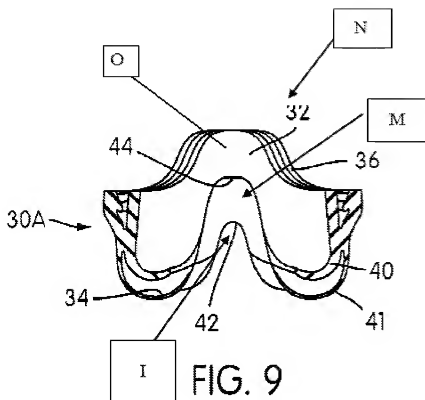
Regarding claim 9, Fig. 3 of Kwok et al. discloses that the inner sealing member (34) has a cut out region ('F') in the upper lip region (see col. 5, lines 24-27, 39-42).

Regarding claim 10 Figs. 1, 3 and 7 of Kwok et al. discloses that the inner sealing member (34) and the outer sealing member (32) are continuously in contact both in use and when not in use around the facial contour contacting region (45; see col. 4, lines 40-59).

Regarding claim 11, Fig. 3 of Kwok et al. discloses that the inner sealing member (34) includes a cheek region ('G' which is between the dotted lines) of the facial contour contacting region (45) wherein the cheek region ('G') is concave (i.e. most clearly seen from the orientation of the dotted lines, the cheek region is concave) so as to accommodate the cartilage extending away from the middle of the nose of a patient.

Regarding claim 12, Figs. 8 and 9 of Kwok et al discloses that the facial contour contacting portion (45) comprises a nasal bridge region (i.e. 'N' which is adjacent notch 42) whereby the nasal bridge region is tapered away from the patient with respect to the remainder of the facial contour contacting portion (as seen from Fig. 9 the nasal bridge region 'N' tapers away from a patient).

Regarding claim 13, Kwok et al. discloses that the nasal bridge region ('N') comprises an inner region ('I'), a middle region ('M') and an outer region ('O') whereby in use the inner region ('I') is most proximate the patient.



Regarding claim 14, Kwok et al. discloses that the inner region ('I'), the middle region ('M') and the outer region ('O') comprise dead space (i.e. regions I, M, and O all comprise cavities or recesses as dead space as shown in Fig. 9).

Regarding claim 15, Kwok et al. discloses that the inner region ('I') comprises a flexible resilient member (i.e. region 'I' as part of the cushion membrane 34 as inner sealing member comprises a resilient flexible material as disclosed in col. 4, lines 40-49) and the middle region ('M') and the outer region ('O') comprise dead space (as again seen from Fig. 9, regions 'M' and 'O' both comprise cavities or recesses as dead space).

Regarding claim 16, Kwok et al. disclosed that the inner region ('I') and the outer region ('O') comprise a resilient deformable material (i.e. inner region 'I' as part of the cushion



membrane 34 as membrane and outer region 'O' as part of the frame 32 as outer sealing member both comprise resilient deformable materials as disclosed in col. 4, lines 40-55) and the middle region ('M') comprises dead space (as seen from Fig. 9, 'M' comprises a cavity or recess as dead space).

Regarding claim 17, Fig. 3 of Kwok et al. discloses that the inner sealing member (34) is adapted to follow the concave portion in the cheek region ('G'; i.e. cushion membrane 34 as inner sealing member is also concave around cheek region 'G').

Regarding claim 18, Figs. 1 and 7 of Kwok et al. discloses that the inner sealing member (34) is adapted to contact the cheek region only when in use (i.e. when the mask is on a user's face and pressure is applied during use, the membrane 34 as inner sealing member, deforms and compresses to be closer to rim 40 of frame 32 as outer sealing member; therefore, the outer region of membrane 34 is compressed during use to touch the inner region 'G' where a user's cheek would touch; col. 4, lines 50-59 and col. 5, lines 25-31).

### ***Conclusion***

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Sprinkle et al. (US Pat. No. 7,290,546 B2) discloses a nasal mask with cushion.

Gunaratnam et al. (US Pat. No. 7,021,311 B2) discloses a mask cushion and frame assembly.

Palkon et al. (US Pat. No. 7,007,696 B2) discloses a mask cushion and method of using the same.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LATOYA LOUIS whose telephone number is (571)270-5337. The examiner can normally be reached on Monday-Friday, 9:30am-7pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe H. Cheng can be reached on 571-272-4433. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. L./  
Examiner, Art Unit 4177  
12/15/2007

/Joe H Cheng/  
Supervisory Patent Examiner  
Art Unit 4177